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- In Review Summary

Date May 20, 2004

To Examiner Kaushal Sumesh
U.S. Patent and Trademark Office
P. O. Box 1450
Arlington, VA 22231

Facsimile number 08919-01600003 / 571-273-0769

From J. Jimmy Hao, Ph.D.

Re HS-40 ENHANCER-CONTAINING VECTOR
Applicant: Chen-Kun James Shen
Application No.: 09/977,432
Filing Date: October 15, 2001
Country: United States
Your Ref.: 13A-870916 (CON)
Our Ref.: 08919-016003

Number of pages including this page 3

Message

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VIA FACSIMILE

May 20, 2004

Examiner Kaushal Sumesh
U.S. Patent & Trademark Office
Commissioner for Patents
Washington, D.C. 20231

Re: HS-40 ENHANCER-CONTAINING VECTOR
Applicant: Chen-Kun James Shen
Application No.: 09/977,432
Our Ref.: 08919-016003

Dear Examiner Sumesh:

Thank you for granting a telephone interview, scheduled for 2:00 pm, May 21, 2004 to resolve issues raised in the Final Office Action and the Advisory Action. This letter is limited to claim 33 to facilitate discussion.

Claim 33 covers a viral expression vector that contains, among others, an enhancer having SEQ ID NO:1 or its complement. You rejected this claim as being obvious over Zhang (which teaches a non-viral expression vector that has a SEQ ID NO:1-containing HS40 enhancer) in view of Miller (which teaches retroviral vectors containing promoters). It is your position that it would have been obvious to one skilled in the art to include in the Miller vectors the HS40 enhancer taught in Zhang.

In the response dated March 22, 2004, we pointed out that it is well known in the art that an enhancer that functions in a non-viral vector, such as the Zhang vector, may not function in a viral vector. As a result, one skilled in the art would not have been motivated to make a viral vector containing an enhancer in the way you suggested. To support this point, we submitted a copy of McCune, which teaches that (1) an enhancer functions well in a non-viral vector, but fails in a viral vector and (2) viral vector sequences are responsible for the failure.

In the Advisory Action, you countered that the "element as taught by McCune is not limited to the responsible element as claimed[,] i.e., SEQ ID NO:1, therefore ... any response other than as taught by McCune would be able [to] function in any viral ... vector." As you correctly pointed out, McCune is not limited to SEQ ID NO:1. Nonetheless, we note that McCune provides a general teaching about inhibiting effects of viral vector sequences on enhancers. See the title. Indeed, McCune specifically teaches that "[its] finding may be applicable to the more general problem of sustaining expression of retrovirus-transduced genes... (see page 4477, column 2, lines 12-13)." Given this general teaching, one skilled in the art would not expect

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that an enhancer, including one containing SEQ ID NO:1, may function in a viral vector, even though it may function well in a non-viral vector. Due to lack of a reasonable expectation of success, one skilled in the art would have not been motivated to include in the Miller vectors the HS40 enhancer taught in Zhang. Thus, Zhang and Miller do not render claim 33 obvious.

As the next deadline falls on May 24, 2004, we would like to expedite the prosecution by inviting your primary Examiner Mr. Jeffrey Fredman to the interview. If you agree, please provide a copy of this letter to him before the interview.

We look forward to speaking to you.

Very truly yours,

Y. Rocky Tsao

Y. Rocky Tsao, Ph..D., J.D.
Reg. No. 34,053

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